

510(k) Summary for CURAD® Silver Bandage

1. SPONSOR

Beiersdorf AG
Hamburg, Germany

Contact Person: Mr. Volker Holle

Date Prepared: May 7, 2004

2. DEVICE NAME

Proprietary Name: CURAD® Silver Bandage
Common/Usual Name: Adhesive Bandages with Drug
Classification Information:

Adhesive Bandages with Drugs have not yet been classified by FDA, but have been given the Product Code "MXI." Adhesive Bandages without added drugs have been designated as Class I devices and exempt from 510(k) submission requirements. Several of the predicate products have been under the Product Code, "FRO." See below.

Names of Related Products	Product Code	21 CFR Ref.	Panel
Nonabsorbable Gauze, Surgical Sponge, and Wound Dressing for External Use (with a Drug)	MXI	None	General/Plastic Surgery
Adhesive Tape and Bandage	KGX	880.5240	General/Plastic Surgery
Dressing	FRO	None	General/Plastic Surgery

3. PREDICATE DEVICES

CURAD® Silver Bandage is substantially equivalent to the following devices:

Silver Strips™ Adhesive Strips	K023609
Actisorb™ Silver 220 Antibacterial Binding Dressing	K022483
Acticoat™ Composite Wound Dressing	K002466 & K983833
Aquacel® Ag with Hydrofiber Silver Impregnated Antimicrobial Dressing	K013814

4. DEVICE DESCRIPTION

The CURAD® Silver Bandage is an adhesive bandage that includes silver in the wound pad. The bandage covers the wound to create a protected environment. At the same time, silver ions reduce bacterial growth in the wound pad.

5. INTENDED USE

The CURAD® Silver Bandage is indicated for first aid to help in minor abrasions, cuts, lacerations, scrapes, and scalds.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

CURAD® Silver Bandage has similar materials to other wound dressings with silver and equivalent concentrations of silver are released. A biocompatibility assessment was performed on the patient-contacting and fluid-path materials of CURAD® Silver Bandage with satisfactory results.

7. PERFORMANCE TESTING

CURAD® Silver Bandage was tested for silver release and antimicrobial effect and was demonstrated to have acceptable results.



FEB 10 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Beiersdorf AG
c/o Mr. Daniel Dillon
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K032463
Trade/Device Name: CURAD[®] Silver Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 14, 2003
Received: November 17, 2003

Dear Mr. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

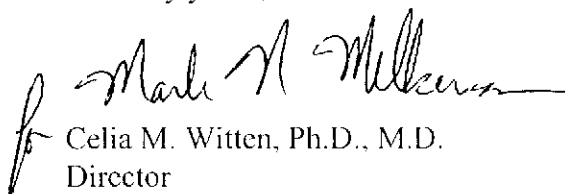
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032463

Device Name: CURAD® Silver Bandage

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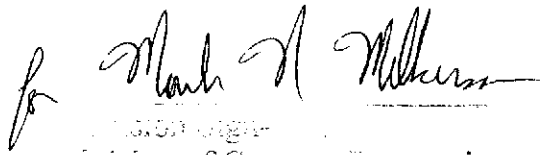
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Mark A. Miller
Division of General Restorative
and Neurological Devices
K032463